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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,817

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02/18/2010

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EXAMINER

SCHELL, LAURA C

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,817	Applicant(s) ALHEIDT ET AL.	
	Examiner LAURA C. SCHELL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-6 and 18-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-6, 18-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/22/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4-6 and 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenwood (US Patent No. 5,120,314) in view of Lynn (US Patent No. 6,228,065). Greenwood discloses the device substantially as claimed including an iv flush syringe assembly (this syringe is perfectly capable of being used for flushing an iv) comprising: a barrel (10) having an inside surface defining a chamber for retaining fluid, an open proximal end (near 15) and a distal end (near 13) including a distal wall with an elongate tip (wall 13, tip 21) extending distally therefrom having a passageway therethrough in fluid communication with said chamber, said inside surface further including a contact area at the distal end of the barrel (Figs. 1, 3 and 6 disclose that the

Art Unit: 3767

contact area is the area 50 at the distal end of the barrel), a plunger (30) including an elongate body portion (32) having a proximal end (near 35), a distal end (near 36) and a flexible stopper (40) slidably positioned in fluid tight engagement with said inside surface of said barrel for drawing fluid into and driving fluid out of said chamber by movement of said stopper relative to said barrel, said elongate body portion extending outwardly from said open proximal end of said barrel (Fig. 1); wherein said contact area has a higher coefficient of friction than said inside surface outside of said contact area for frictionally engaging said stopper when said stopper is in contact with said distal wall of said barrel for frictionally holding said stopper in a partially deflected position to prevent reflux of the fluid back into the chamber after fluid has been delivered from said chamber (Figs. 1-10 disclose that the inside surface of the barrel at area 50 has a portion with multiple tabs such as 67 in fig. 6 and 82 in Fig. 10, wherein the tabs are discontinuous with the inner surface of the barrel and therefore provide an area of higher coefficient of friction. The tabs engage with the plunger 42 as seen in Fig. 10, and col. 5, lines 39-45 disclose that the tabs "dig into the elastic piston 40" which therefore indicates that the digging in of the tabs partially deforms/deflects the piston, and this action keeps the piston at the distal end of the barrel preventing reflux of fluid), wherein the diameter of the outer surface of each portion of the stopper is less than or equal to the largest diameter of the inside surface of the distal end of the barrel having the contact area when the stopper is in the partially deflected position (Fig. 10 discloses that the outside diameter of 42 is equal to or less than the diameter of the interior surface of the barrel wall). Greenwood, however, does not disclose that the contact

Art Unit: 3767

surface on the inside surface of the barrel is integral with the inside surface of the barrel. Lynn, however, discloses a contact surface on an interior surface of the syringe barrel (Fig. 13, projections 220/278) which are integral with the surface of the barrel (claim 19 states that they are integral). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Greenwood's contact area by making it integral with the inside surface of the barrel, as taught by Lynn, in order to make sure that the contact area does not accidentally become dislodged/break away from the inside surface and therefore render the device's protection system useless. Also, it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art.

In reference to claim 5, Greenwood discloses that the contact area includes a plurality of annular deformations (the area above and below ring portion 64 in Fig. 6, for example, discloses at least 2 annular deformations).

In reference to claim 6, Greenwood discloses that the annular deformations are annular projections on said inside surfaces of said barrel (Figs. 1-10).

In reference to claim 22, Greenwood discloses that the stopper is made from rubber (col. 4, lines 57-58).

In reference to claim 23, Greenwood discloses that the stopper can be removed from said contact area after said stopper has contacted said distal wall of said barrel (if one were to use enough force, one could pull the stopper out of the barrel. The stopper may be damaged by doing this, but Applicant has not claimed such).

Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenwood (US Patent No. 5,120,314) in view of Lynn (US Patent No. 5,522,804). Greenwood discloses the device substantially as claimed except for a tip cap and flush solution. Lynn, however, discloses a flushing syringe (Figs. 13 and 7c) with a tip cap (Fig. 7c, 124) and flushing solution in the chamber of the syringe, wherein the flushing solution is saline (Fig. 7c, 130; Fig. 7c discloses that the syringe obtains the flush solution, saline (130) from the pouch by drawing it into the chamber area (seen in Fig. 7c as area 26), as better described by Col. 14, lines 20-30). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Greenwood with a cap and the use of saline solution, as taught by Lynn, in order to seal the end of the syringe and to provide the syringe with a flushing solution, since the syringe of Palmer is structurally equivalent to a flushing syringe and is therefore perfectly capable of being used as a flushing syringe.

Response to Arguments

Applicant's arguments filed 12/4/2009 have been fully considered but they are not persuasive. In response to Applicant's arguments that the Lynn reference does not disclose that the projections (220 in Fig. 13) are integral with the barrel, it is the examiner's opinion that even if Applicant feels that claim 19 does not provide enough support, that it is clear from Fig. 13's cross-section of the barrel that projections 220 are formed as part of the interior surface of the barrel and therefore are integral with the

Art Unit: 3767

barrel. In response to Applicant's arguments that Lynn does not disclose that the projections 220 would deflect the stopper, the examiner would like to point out that the Lynn reference was not brought in to teach deflection of the stopper, that is taught by the Greenwood reference. Instead the Lynn reference was brought in to teach that it is known in the art to make projections which would hold a stopper in place by extending from the interior surface of the barrel, integral. In response to Applicant's arguments that it would not have been possible to make the annular ring with projections integral with the barrel, it is still the examiner's position that it would have been possible to take the inserts of Greenwood (such as in Figs. 6 and 10) and instead of merely bonding them to the barrel, make them integral with the barrel such that they project from the inner barrel's wall, as this would have only involved making an annular ring integral with the barrel wall and making downwardly angled projections integral with the annular projection/wall.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 3767

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767
/Kevin C. Sirmons/

Application/Control Number: 10/530,817

Page 8

Art Unit: 3767

Supervisory Patent Examiner, Art Unit 3767